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Patrick W. Truitt

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EXAMINER

DIXON, ANNETTE FREDRICKA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/623,336	Applicant(s) TRUITT ET AL.	
	Examiner Annette F. Dixon	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 24 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 24 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response the amendment filed on March 26, 2010. Examiner acknowledges claims 1-15, 24, and 31-33 are pending, with claims 1, 2, 8, 9, and 24 having been currently amended, and claims 16-23 and 25-30 having been cancelled.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 31 and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by Woodring et al. (WO99/13932).

As to Claims 31 and 33, Woodring discloses a medical ventilator having a source of breathable gas (ambient air, via ambient air inlet 34), a pressure generator (38) comprising a motor (86), a rotatable drive shaft (88) driven by the motor (86), and an impeller (74, 76, and 78) for a patient circuit (Figure 2, inspiratory line 28 and expiratory line 30) wherein the output flow ranges may be set between 3 and 140 liters per minute and the output pressure ranges may be set between 5 and 35 centimeters of water for the purpose of providing ventilation control consistent with the respiratory therapy needs of the patient. (Page 15, Lines 9-16).

4. Claims 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by DeVries et al. (5,868,133).

As to Claims 31 and 33, DeVries discloses a source of breathing gas (oxygen, via 26, and ambient air, via 24); a pressure generator (14), comprising: a motor (102), a rotatable drive shaft (114) driven by the motor (102), and an impeller (104) mounted on the drive shaft (114) (Column 17, Lines 20-39); pressure generating operation ranges of air flow 10-140 liters per minute (Column 10, Lines 47-48) and pressure flow 1 to 60 centimeters of water (Column 11, Lines 29-30); and supplying the pressurized gas through a patient circuit (via line 22). (Figure 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 7-11, 13-15, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pauly (5,741,123) in view of Blair (4,653,976).

As to Claims 1, 4, and 7, Pauly discloses a radial impeller (30, Figures 2 and 3), comprising a hub (38) attachable to a rotating shaft (16, Column 2, Lines 37-38); an impeller body (30) attached to the hub (38) and extending radially from the hub (38) to a perimeter of the impeller (the location of element 56) and having opposed radial faces;

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and a plurality of impeller blades (48) disposed on one face of the impeller body (30), each impeller blade (48) extending from a leading end (44) of the blade generally adjacent to the hub (38) toward a trailing end (56) generally at the perimeter of the impeller, wherein the plurality of impeller blades decrease in height from the leading end to the trailing end (as shown in Figure 3), wherein an inlet area is defined between each pair of adjacent blades (48_n and 48_{n+1}) generally adjacent to the hub (38), with each inlet area being defined as the area at the radius of the leading end (44) of the adjacent blade (48_n and 48_{n+1}) and the one face of the impeller body (30) and wherein an outlet area defined between the pair of adjacent blades (48_n and 48_{n+1}) as the area at the radius of the trailing end (56) of the (48_n and 48_{n+1}) and the one face of the impeller body (30) wherein each inlet area is substantially equal to each corresponding area for each of (48_n and 48_{n+1}). (Figures 2 and 3). Yet Pauly does not expressly disclose a second plurality of impeller blades on the impeller body having a shape partial to the first plurality of impeller blades. Blair teaches an impeller (Figure 2) having a first set of impeller blades (38) and a second set of impeller blades (40) which are partial blades of the first larger set of impeller blades (38) for the purpose of preventing excessive diffusion of the gas flow as the air channels increase in size with the increasing impeller circumference from the air inlet to the exit. (Column 3, Lines 25-30). Therefore, it would have been obvious to one of ordinary skill in the art to modify the impeller blades of the impeller of Pauly to include a second partial set of impeller blades, as taught by Blair for the purpose of preventing excessive diffusion of the gas profile.

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As to Claims 2 and 9, the modified Pauly discloses an impeller having first full and second partial sets of impeller blades; yet, does not expressly disclose the midpoint of the first full set of impeller blades to be the start of the second partial set of impeller blades for the purpose of preventing excessive diffusion (Blair: Figure 2, Column 3, Lines 25-30). In light of the relationship between the impeller blades and the ability to prevent excessive diffusion, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the appropriate location with respect to desired level of diffusion prevention, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Moreover, Applicant has not asserted the specific location of the second partial set of impeller blades at the midpoint of the first full set of impeller blades recited provides a particular advantage, solves a stated problem or serves a purpose different from that of preventing excessive diffusion, thus the use of the specific location lacks criticality in its design. Consequently, one of ordinary skill in the art would have expected Applicant's invention to perform equally well with the modified Pauly. Therefore, it would have been obvious to one having ordinary skill in the art to modify the location of the second partial set of impeller blades of the modified Pauly a known result effective variable in order to provide a location of the second partial set of impeller blades capable of preventing the desired amount of diffusion in the gas profile.

As to Claims 3 and 10, Pauly discloses an axially extending skirt (42) attached to the impeller body (30) on an opposite face. (Figure 3).

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As to Claims 8, 11, and 15, please see the rejection of claim 1. The difference between claims 8, 11, and 15 and claim 1 is the incorporation of a housing having a gas inlet and gas outlet. Pauly discloses an impeller (30) mounted within a housing (28) having a gas inlet (34) and a gas outlet (via 32).

As to Claims 13 and 14, Pauly discloses the housing (28) having a gas inlet (34) that increases around the perimeter of the impeller where the height of the blades follows the contour of the housing. (Figure 1).

As to Claim 24, please see the rejection of claim 1. The difference between claim 24 and claim 1 is the incorporation of a source of gas. Pauly discloses the source of gas is air. (Figure 1).

7. Claims 5 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Pauly (5,741,123) in view of Blair (4,653,976), as applied to claims 1 and 8, and further in view of Wassmann (3,751,179).

As to Claims 5 and 12, the modified Pauly discloses the hub (38) for a radial impeller; yet does not expressly disclose the shape of the hub having a smooth outer surface that curves radially outlet toward the plurality of inlets. Wassmann teaches the hub (42) having a curved shape (40) attached thereto prior to the plurality of impeller blades for the purpose of providing a central structure by which the drive shaft and bearing sealing structure is attached to the impeller blades of the pump. (Column 2, Lines 60-67). In light of the relationship between the shape of the hub and the ability to receive the drive shaft for the impeller blades, it would have been an obvious matter of design choice to make the different portions of the hub of whatever form or shape was

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desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape of the hub of the modified Pauly to include a curved shape as taught by Wassmann as a shape that can effectively support the bearing and sealing structure of the impeller blades on to the drive shaft.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pauly (5,741,123) in view of Blair (4,653,976), as applied to claim 1, and further in view of Cordts (5,224,823).

As to Claim 6, the modified Pauly discloses an impeller made from a one-piece construction (Column 3, Lines 31-37); yet does not expressly disclose the one piece construction of the impeller to be made by injection molding. Cordts teaches impellers may be made of metal or plastics wherein the plastic materials may be made by injection molding or any other advantageous production methods without compromising the mechanical strength of the impeller. (Column 2, Lines 15-21). Therefore, it would have been obvious to one having ordinary skill in the art to modify the method of construction of the one piece impeller of the modified Pauly, to be made by injection molding as taught by Cordts as an alternative material construction method.

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9. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Woodring et al. (WO99/13932) in view of Axe et al. (6,085,747).

As to Claim 32, Woodring discloses a pressure generating system, yet, does not expressly disclose the standard deviation of the pressure from the pressure generating system to be not greater than 1.5 centimeters of water. Axe teaches the relationship between the standard deviation and the disturbances in the pressure profile during operation in order to control the operation of the pressure generator. (Column 4, Lines 29-44). In light of the relationship between the standard deviation and the disturbances of pressure, it would have been obvious to one having ordinary skill in the art to at the time the invention was made to select the specific standard deviation threshold with respect to the disturbances of pressure in order to effectively control the pressure generator, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Moreover, Applicant has not asserted the specific operational standard deviation recited provides a particular advantage, solves a stated problem or serves a purpose different from providing a control means for efficiently operating the pressure generator, thus the use of the specific location lacks criticality in its design. Consequently, one of ordinary skill in the art would have expected Applicant's invention to perform equally well with the modified Woodring. Therefore, it would have been obvious to one having ordinary skill in the art to modify the standard deviation threshold operational ranges of the pressure generator of the modified

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Woodring a known result effective variable in order to provide a operational control system respective of the disturbances of pressure.

10. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries et al. (5,868,133) in view of Axe et al. (6,085,747).

As to Claim 32, DeVries discloses a pressure generating system, yet, does not expressly disclose the standard deviation of the pressure from the pressure generating system to be not greater than 1.5 centimeters of water. Axe teaches the relationship between the standard deviation and the disturbances in the pressure profile during operation in order to control the operation of the pressure generator. (Column 4, Lines 29-44). In light of the relationship between the standard deviation and the disturbances of pressure, it would have been obvious to one having ordinary skill in the art to at the time the invention was made to select the specific standard deviation threshold with respect to the disturbances of pressure in order to effectively control the pressure generator, since it has been held that where general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Moreover, Applicant has not asserted the specific operational standard deviation recited provides a particular advantage, solves a stated problem or serves a purpose different from providing a control means for efficiently operating the pressure generator, thus the use of the specific location lacks criticality in its design. Consequently, one of ordinary skill in the art would have expected Applicant's invention to perform equally well with the modified DeVries. Therefore, it

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would have been obvious to one having ordinary skill in the art to modify the standard deviation threshold operational ranges of the pressure generator of the modified DeVries a known result effective variable in order to provide a operational control system respective of the disturbances of pressure.

Response to Amendment

11. The amendment filed on March 26, 2010 includes evidence of common ownership disqualifying prior art reference 6,543,449 as seen on Page 11 of Applicant's remarks. However, it should be noted, prior art reference 6,543,449 shares the same priority application as WO99/13932 also known as PCT/US98/19635 having a publication date of March 25, 1999. Consequently, a new rejection utilizing the WO99/13932 (a 35 U.S.C. 102(a) reference not eligible for the common ownership exclusion) has been made and this office action has been made non-final.

Response to Arguments

12. Applicant's arguments with respect to claims 1-15, 24, and 31-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Blair et al. (4,653,976) and Ribaud (3,904,308) disclose an impeller having a first plurality of impeller blades wherein the blades decrease in height

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from the leading end near the hub to the trailing end near the perimeter of the impeller and have a second plurality of impeller blades near the middle of the first plurality of impeller blades leading to the trailing end near the perimeter of the impeller.

Additionally, Rapoport (5,065,756) discloses a blower having a flow rate and pressure output partially coextensive by the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon

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Examiner
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/Annette F Dixon/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771